Hot Topics in Endovascular Intervention: Guideline Changes and Emerging Techniques

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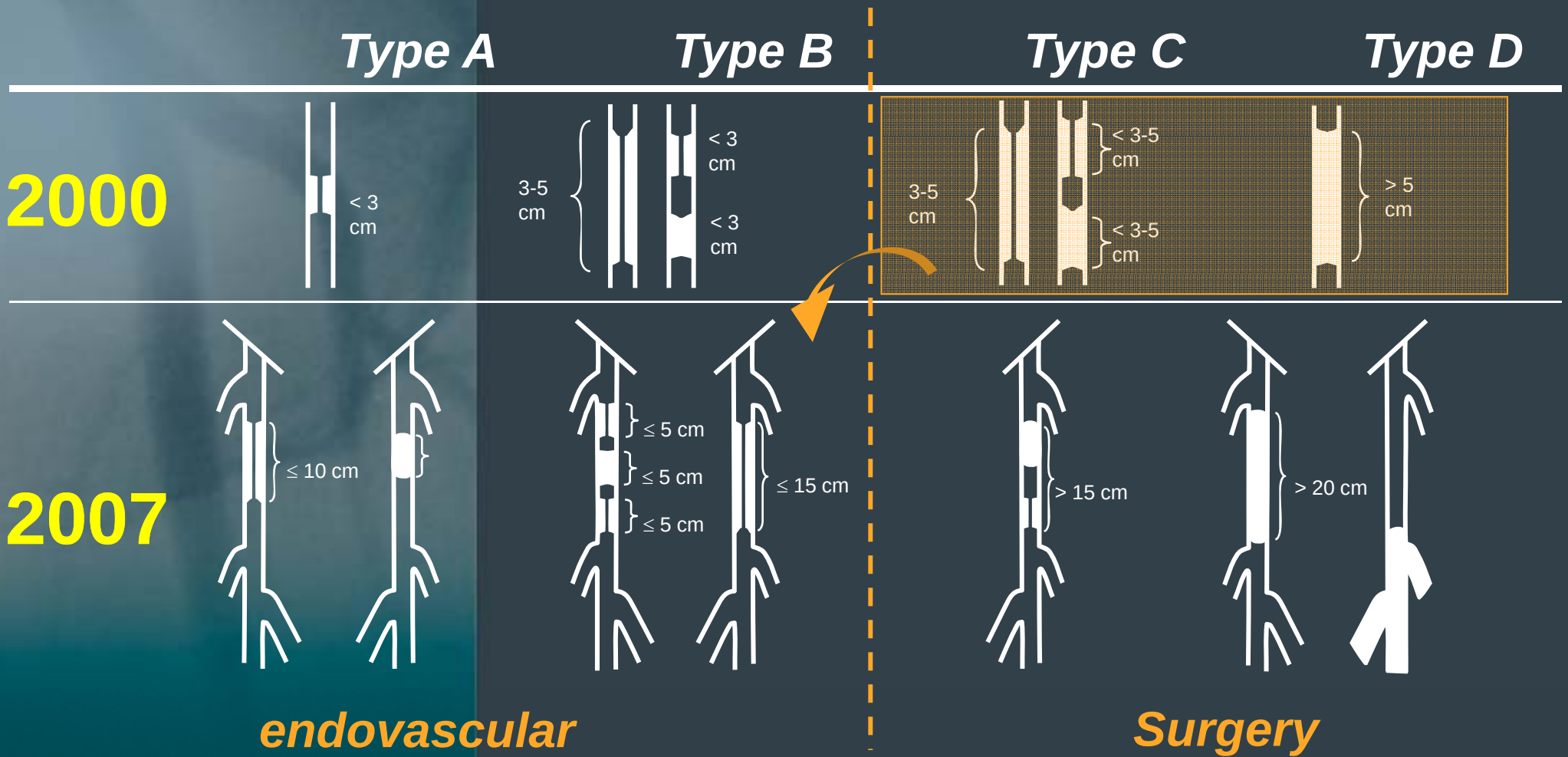
TASC-Recommendations for the Femoropopliteal Tract



Published Data for SFA-Angioplasty 2006
(to be used for the TASC-II consensus discussion)

Balloon Angioplasty versus Implantation of Nitinol Stents in the Superficial Femoral Artery

Martin Schillinger, M.D., Schila Sabeti, M.D., Christian Loewe, M.D., Petra Dick, M.D., Jasmin Amighi, M.D., Wolfgang Mlekusch, M.D., Oliver Schlager, M.D., Manfred Cejna, M.D., Johannes Lammer, M.D., and Erich Minar, M.D.

New Engl J Med 2006;354:1879-1888

Initial clinical experience with an IVUS-guided transmembrane puncture device to facilitate recanalization of total femoral artery occlusions

D. Scheinert, MD; S. Bräunlich, MD; S. Scheinert, MD; M. Ulrich, MD; G. Biamino, MD; A. Schmidt, MD

EuroIntervention 2005;1:115-119

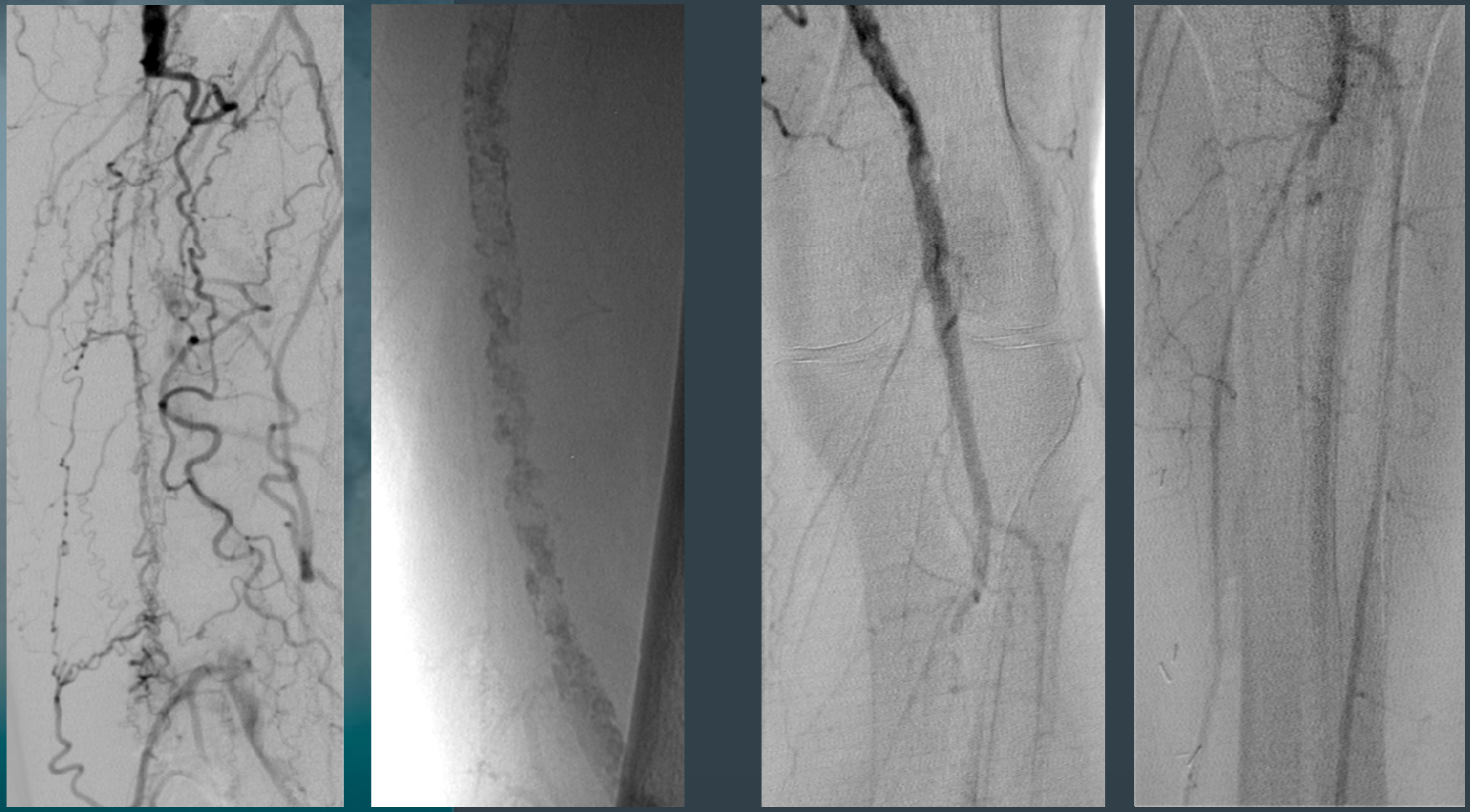
Not mentioned in the TASC-II document

Recommendations for SFA-Angioplasty

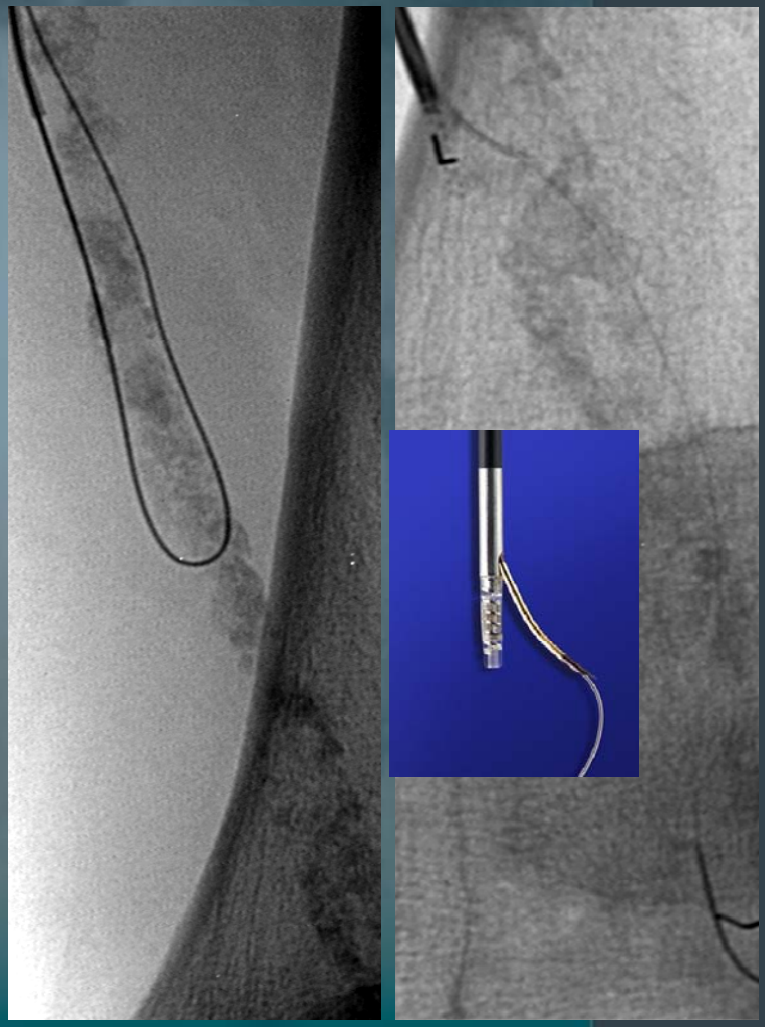
Re-Entry-devices and drug-eluting devices for SFA-treatment were not available for TASC-II Consensus.

TASC IIb	no consensus achieved
TASC III	in progress

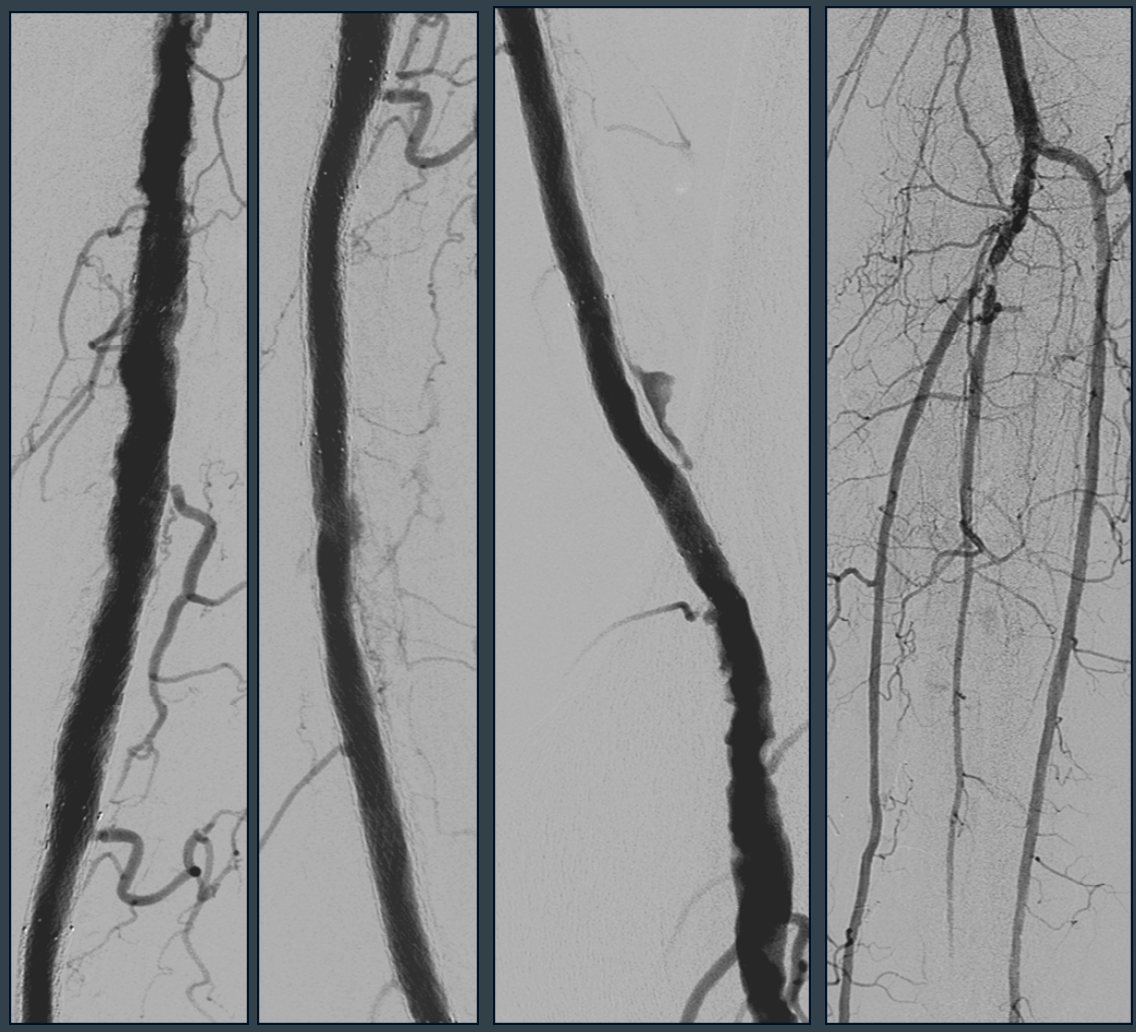
Highly complex SFA-CTOs after TASC-II



PTA for Highly complex SFA-CTOs



Outback-catheter



at 28 months assisted patency

Patency-Rate after PTA of Complex SFA-CTOs

- Registry of SFA-CTOs with
  - Outback-recanalization and
  - Standard nitinol-stents

- Mean occlusion-length
  192 ± 92 cm

- Residual stenosis > 30%
- in **43 %** due to calcification

Bausback et al. *JEVT* 2011

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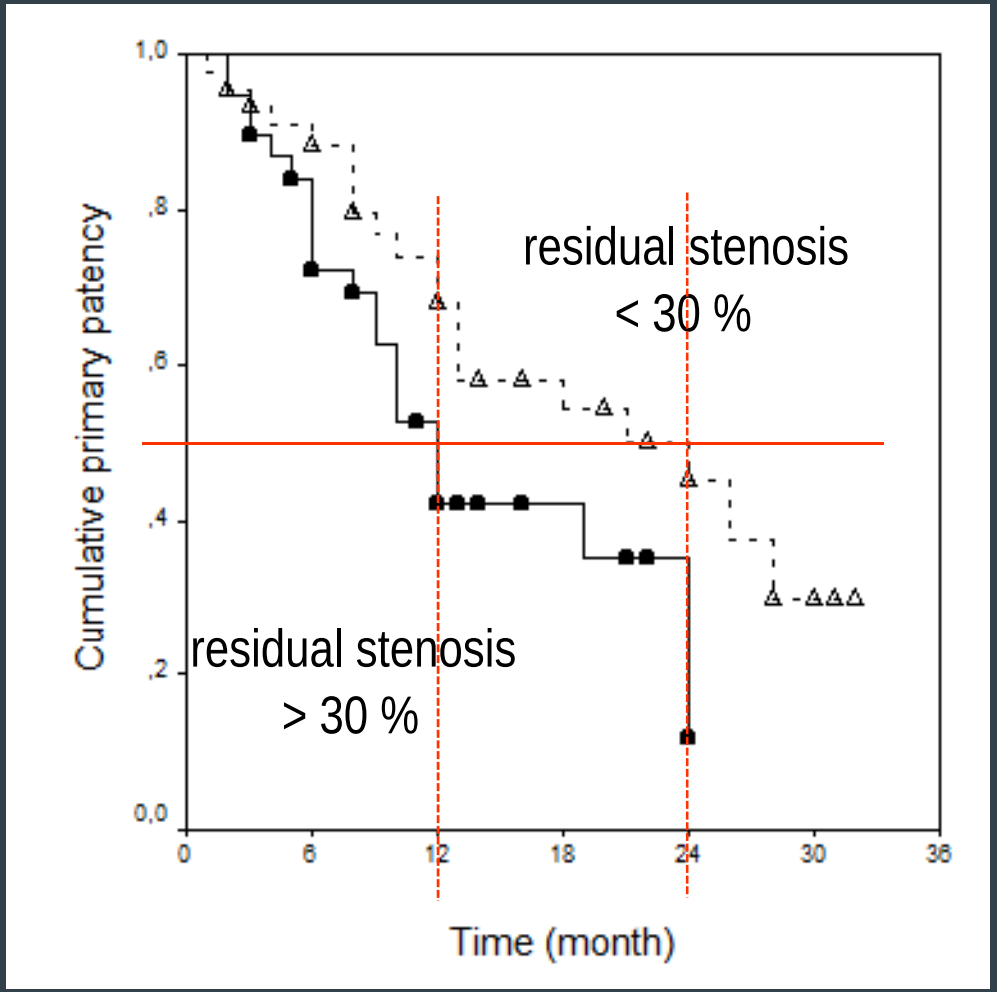


Bausback et al. *JEVT* 2011

New Techniques for SFA-PTA since TASC II

Crossing-tools

- Ocelot
- Crosser
- OCT-crossing-device

Atherectomy-devices

- TurboHawk
- Booster-Laser
- Jetstream
- CSI

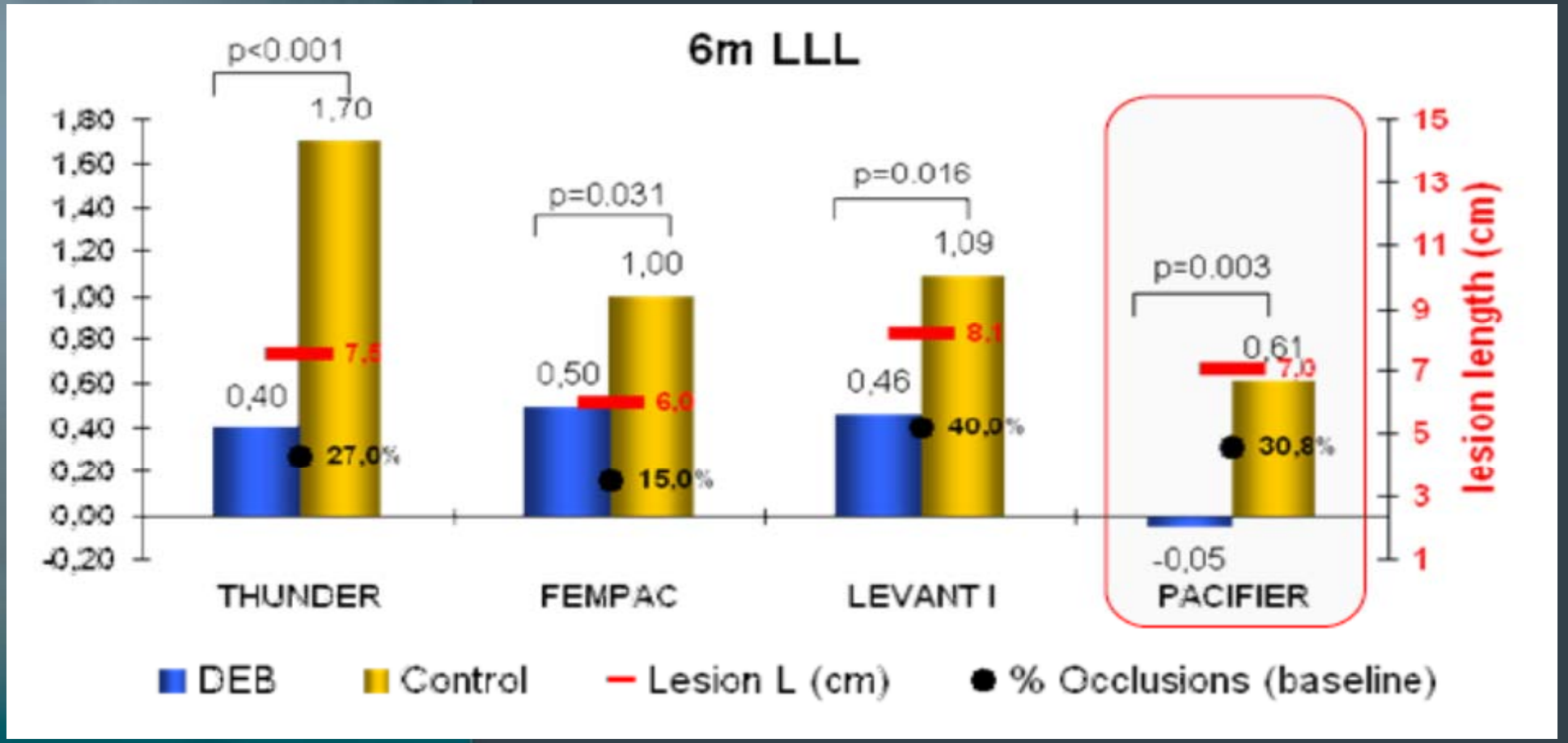
New balloon-technologies

- Drug-eluting balloons
- Scoring-balloons

New stent-technologies

- 2.-generation nitinol-stents
- Supera-stent
- Samba-stent
- Flex-stent
- Zilver-PTX
- Heparin-coated Viabahn

Randomized Trials
DEB vs. Conventional Balloon



Werk et al. CIRSE 2011

Long SFA-Lesions: DEB or DES?

16 cm
TASC C

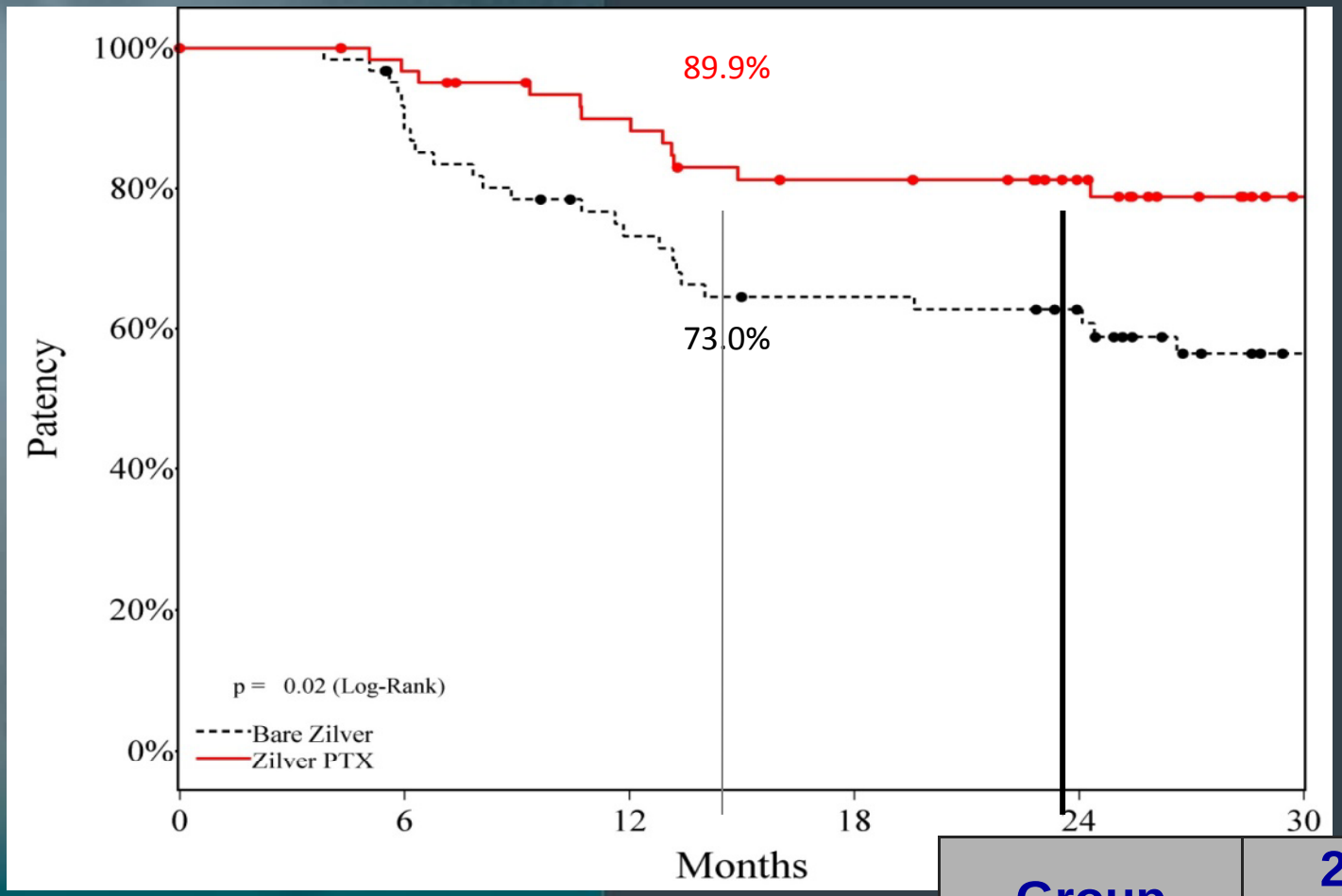
Surgery recommended (TASC II)

Mean lesion-length of the
4 RCTs DEB vs. standard balloon

	Lesion-length
Thunder	7.5 cm
FemPac	5.7 cm
Levant I	8.1 cm
Pacifier	7.0 cm

TASC A and B lesions

Zilver® PTX™ vs. Bare Metal Zilver-Stent



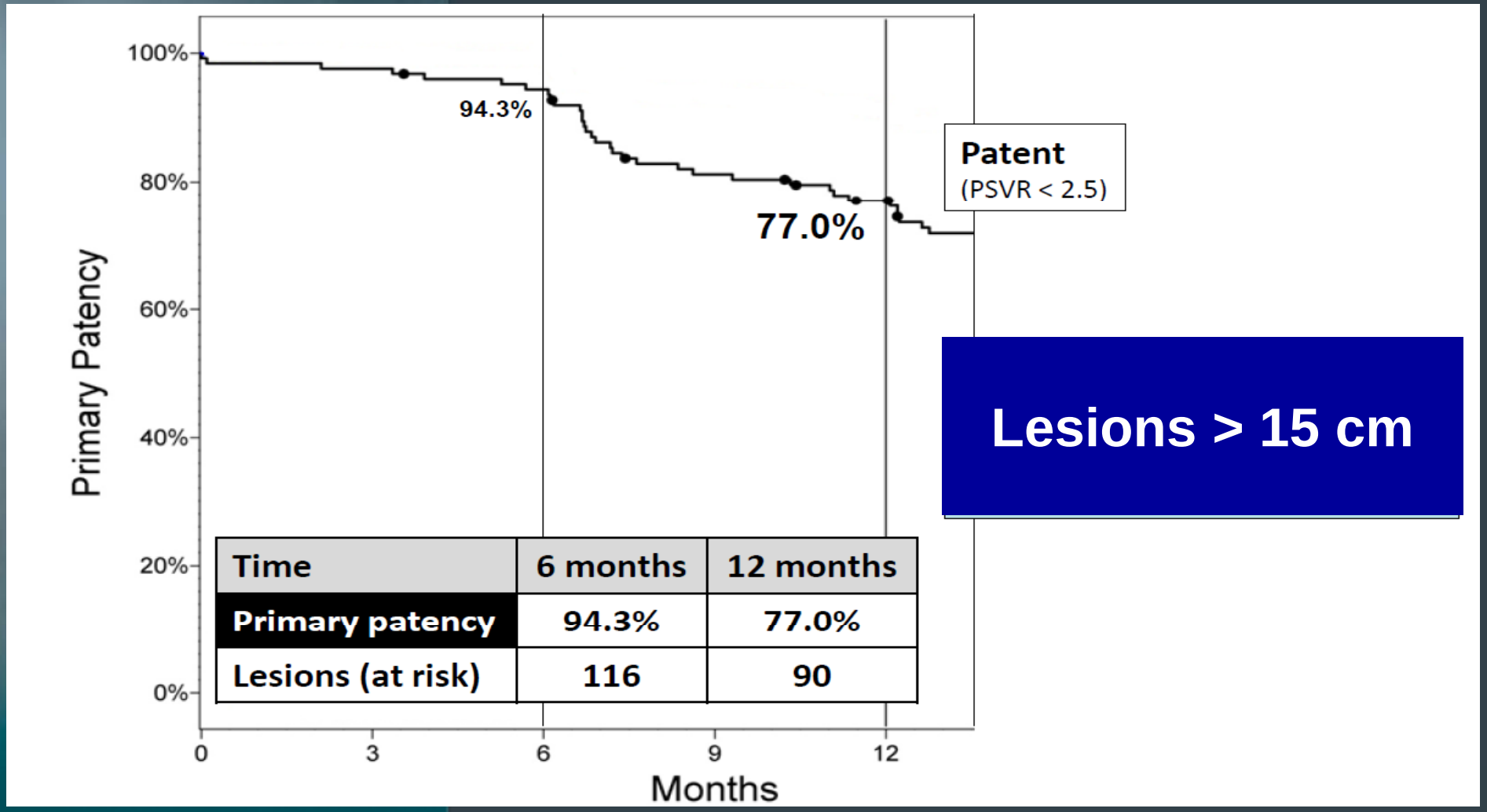
81.2% (Provisional Zilver PTX, n = 47 lesions)

62.7% (Provisional Bare Zilver, n = 54 lesions; p < 0.01 vs. Zilver PTX)

Mean lesion-length 65 mm

Group	24 month Restenosis	
	Rate	Reduction
Zilver PTX	18.8%	50%
Bare Zilver	37.3%	

Zilver-PTX for Long SFA-Lesions
Data from the single arm registry

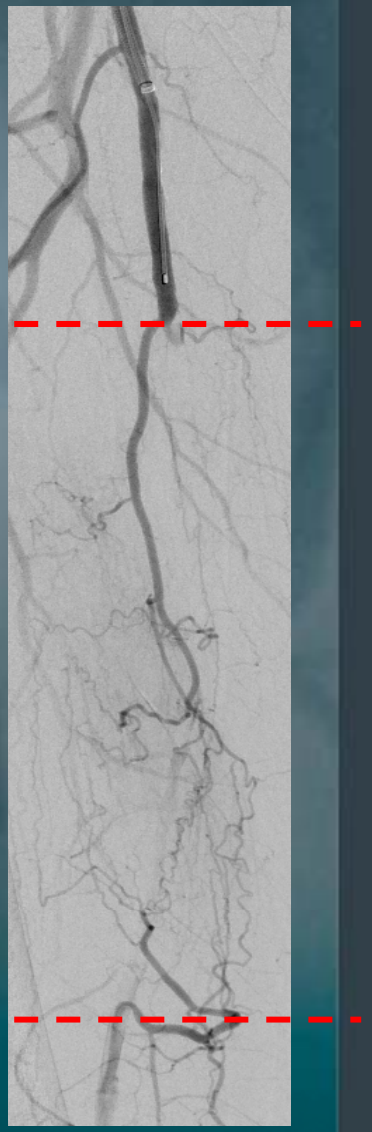


Time	6 months	12 months
Primary patency	94.3%	77.0%
Lesions (at risk)	116	90

Lesions > 15 cm

Indications for Zilver-PTX Stent

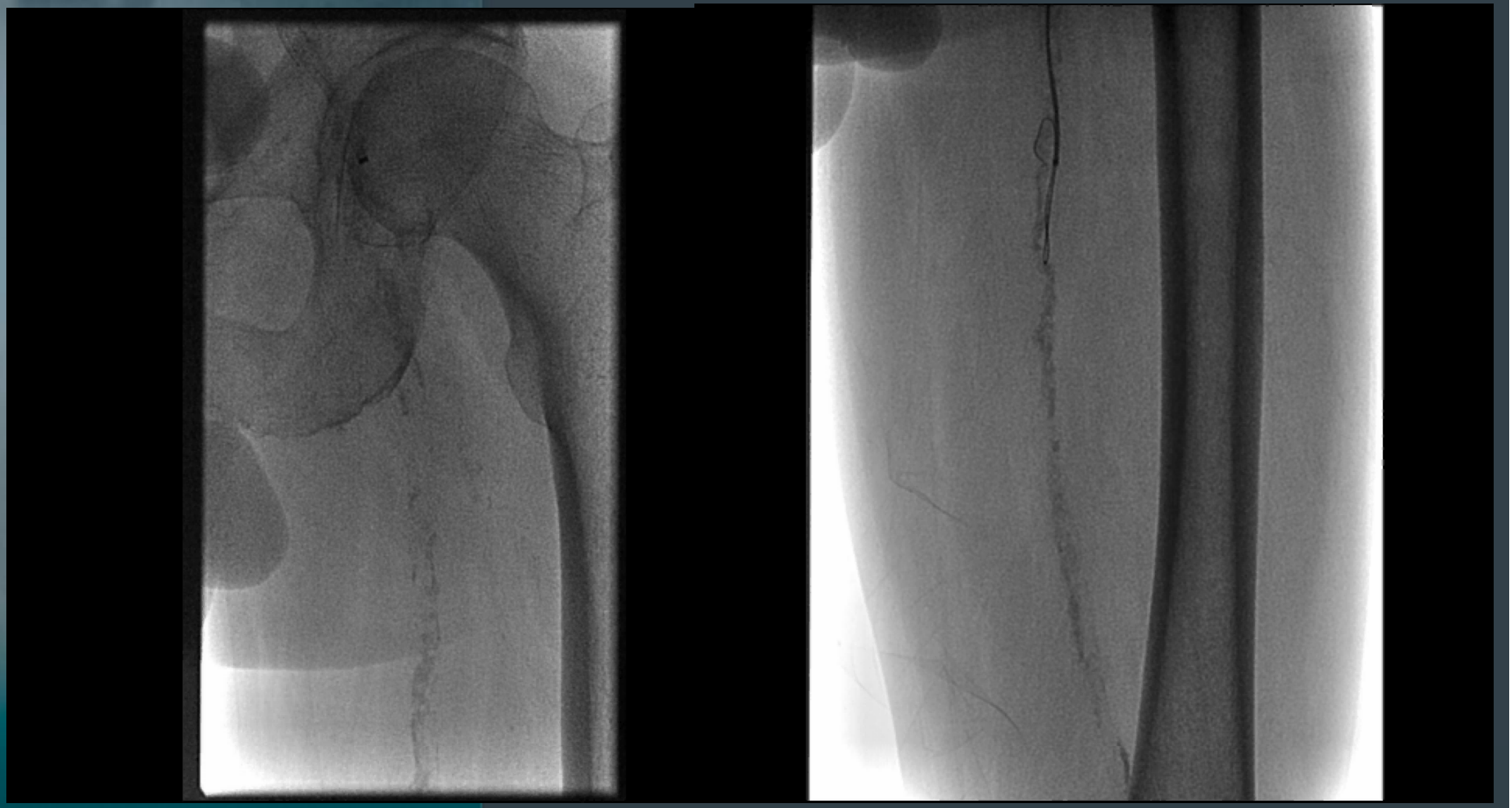
16 cm
TASC C



After PTA

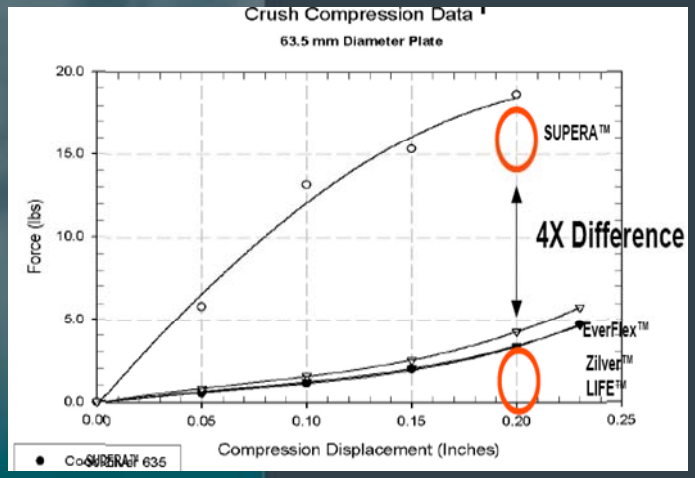
Zilver-PTX 6/120 + 6/60

Long Calcified SFA-Occlusions (TASC D Lesion)

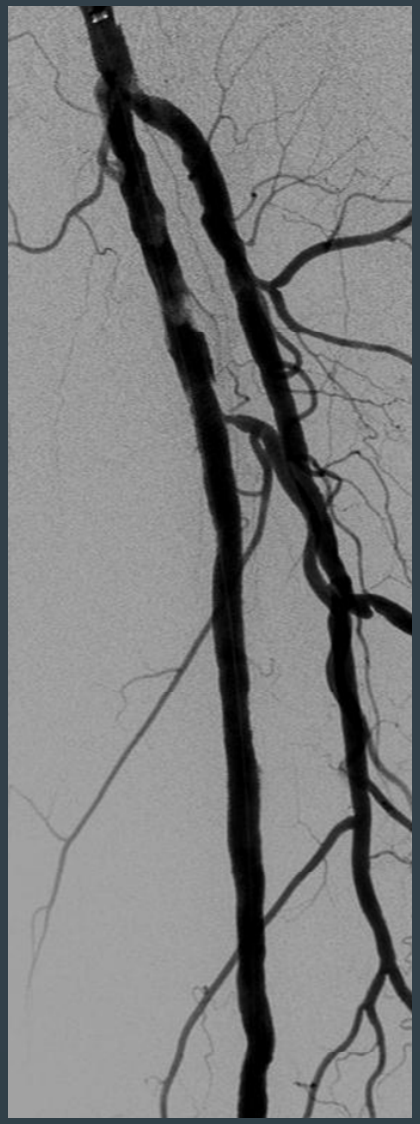


Supera-Stent for Complex SFA-Leisons

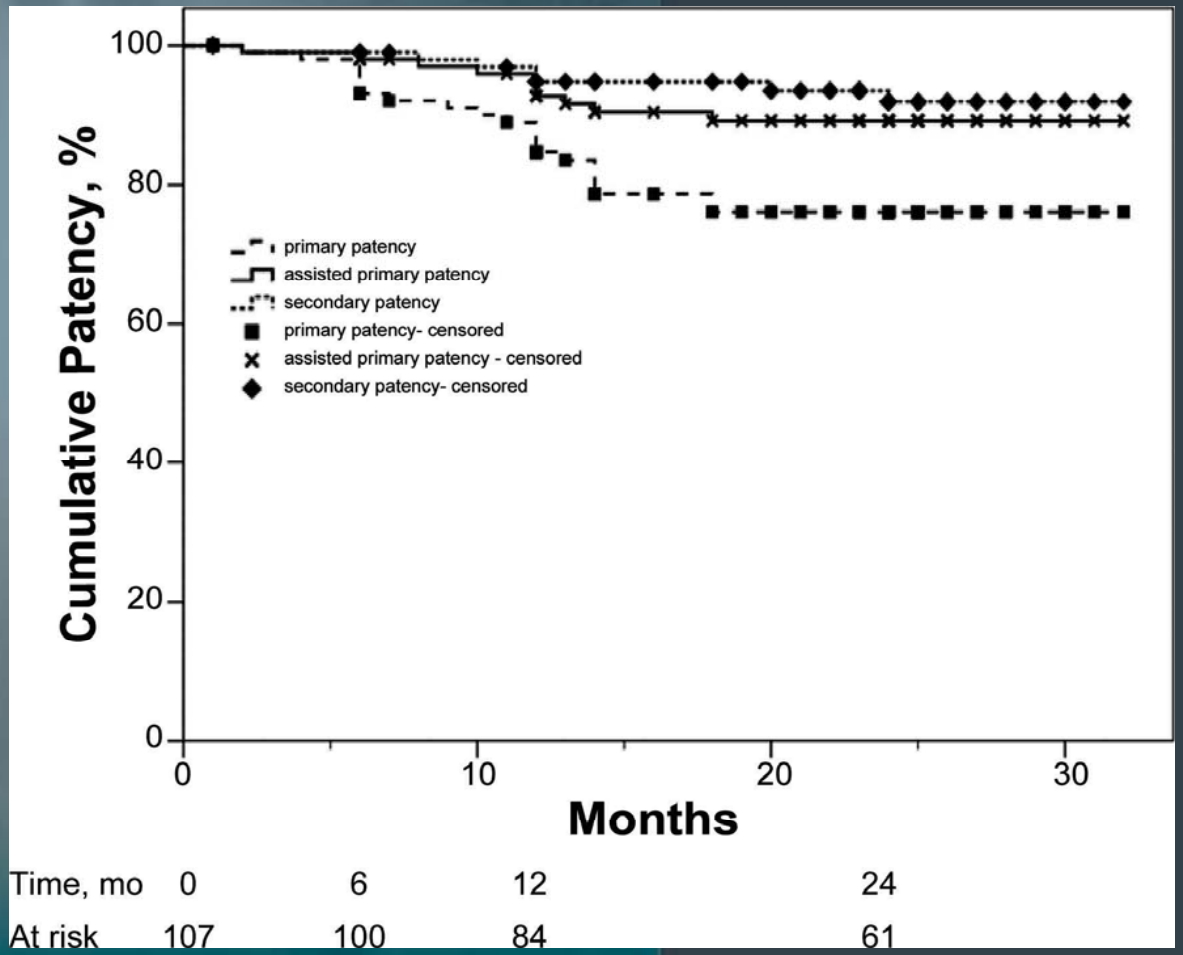
after 5mm-Balloon-PTA



Supera (IDEV)



Supera-Stent for Treatment of the SFA

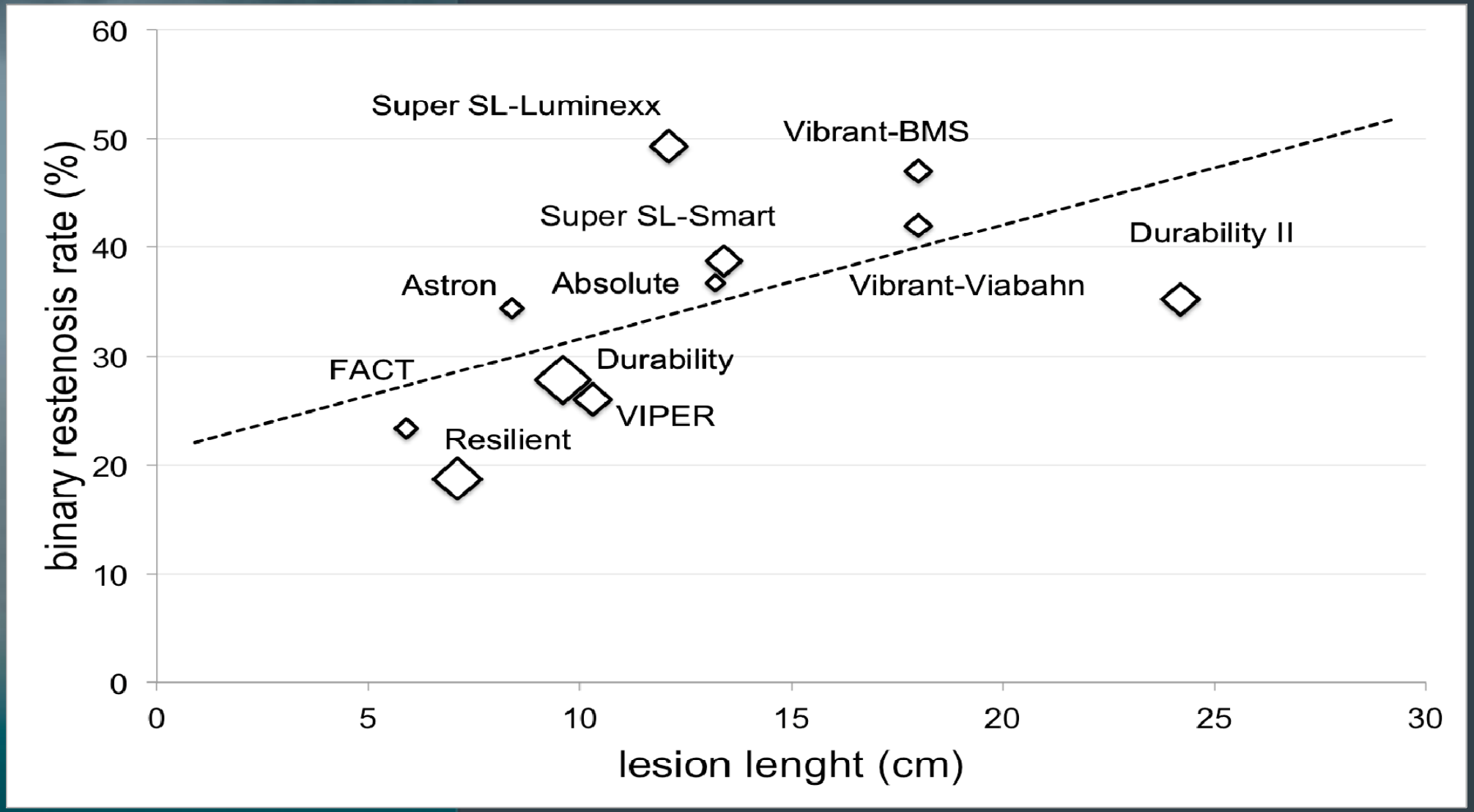


Mean lesion-length: 90.2 mm

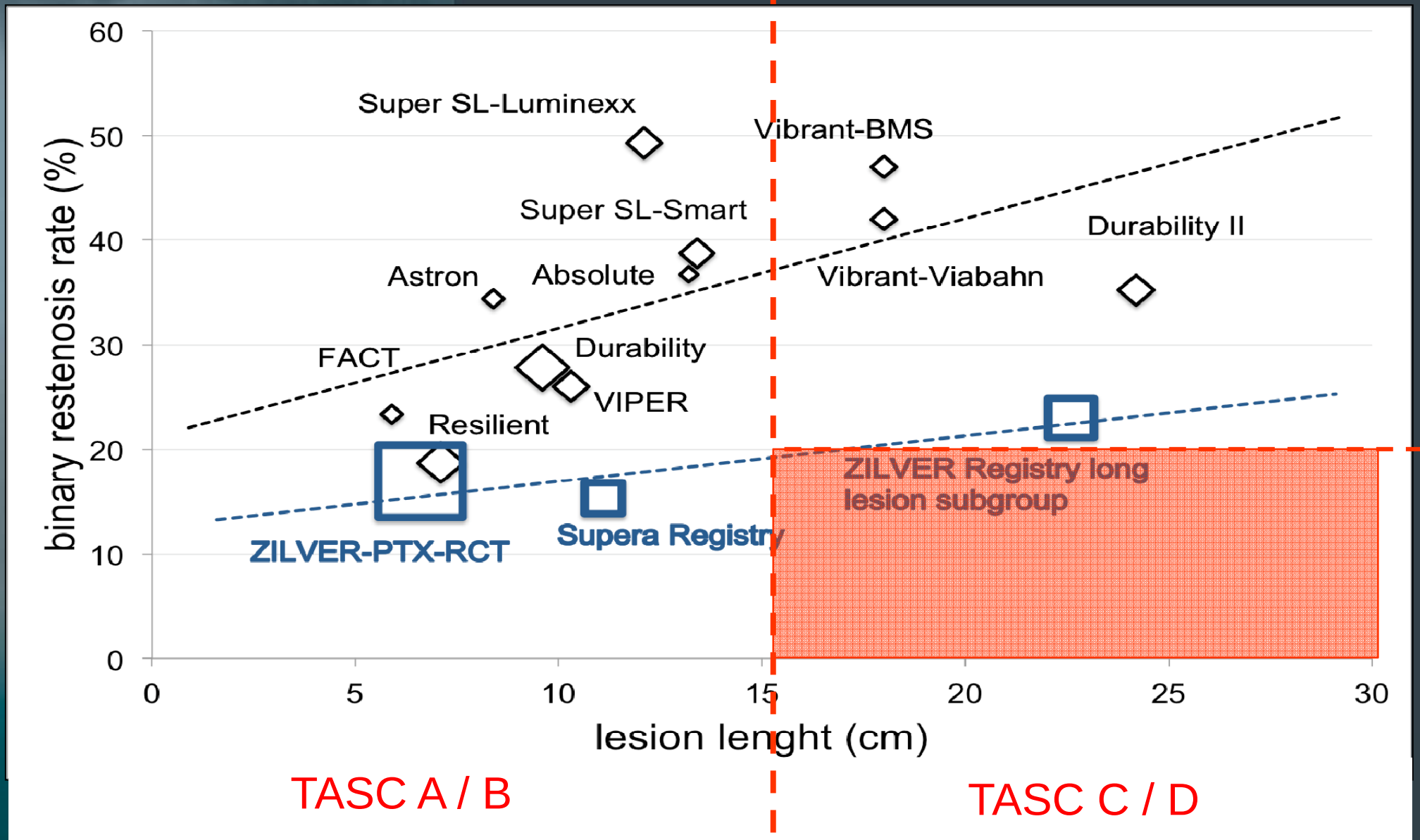
Mean stent-length: 111 mm

Supera-registry: Scheinert et al., JEVT 2011

Binary Restenosis at 12 Mo in SFA Stenting Trials



Binary Restenosis at 12 Mo in SFA Stenting Trials



Should Existing Guidelines be modified in the Light of New Technologies ?

- Results for SFA-PTA have improved since TASC II
- Yet only few data for long SFA-lesions available
- TASC-C and –D lesions might be treated endovascular
  - in patients with critical limb ischemia
  - may be not yet in claudicatio-patients

Recommendations for Infrapopliteal Recanalization TASC-I 2000

Lesion-Morphology	Recommendations
Single Stenosis < 1cm	**PTA**
Multiple Lesions < 1cm short infrapop. stenosis + fem. PTA	Insufficent data for clear recommendations
Singular stenosis 1-4 cm Occlusions 1-2 cm	Insufficent data for clear recommendations
Single Occlusion > 2 cm	**Surgery**

Trans**A**tlantic Inter-**S**ociety **C**onsensus – *J Vasc Surg* **2000**

TASC-II Recommendations for Treatment of BTK-Arteries

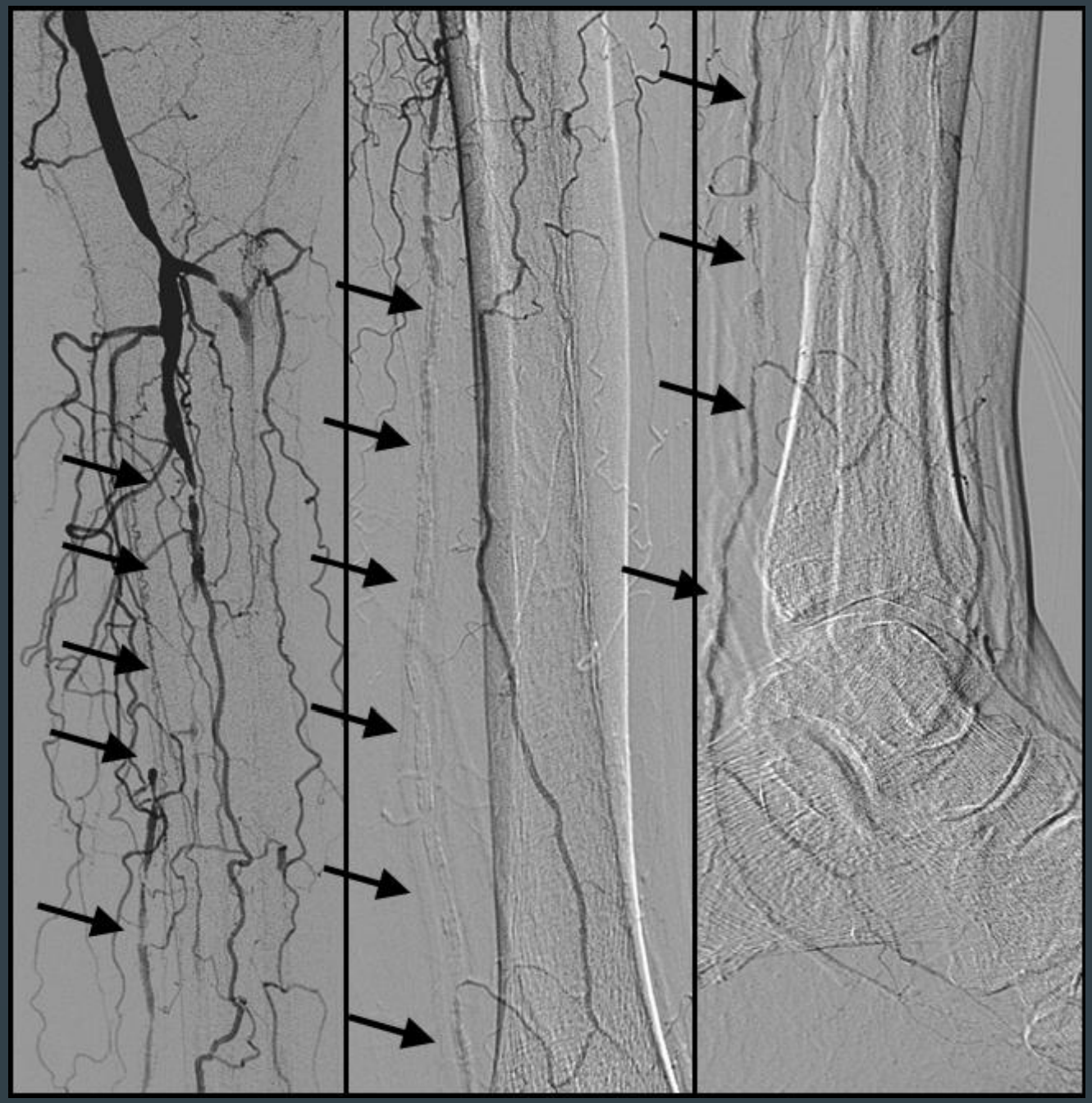
Recommendation 35:
If endovascular recanalization and open repair/bypass give equivalent short- and long-term improvement, endovascular techniques should be used first.

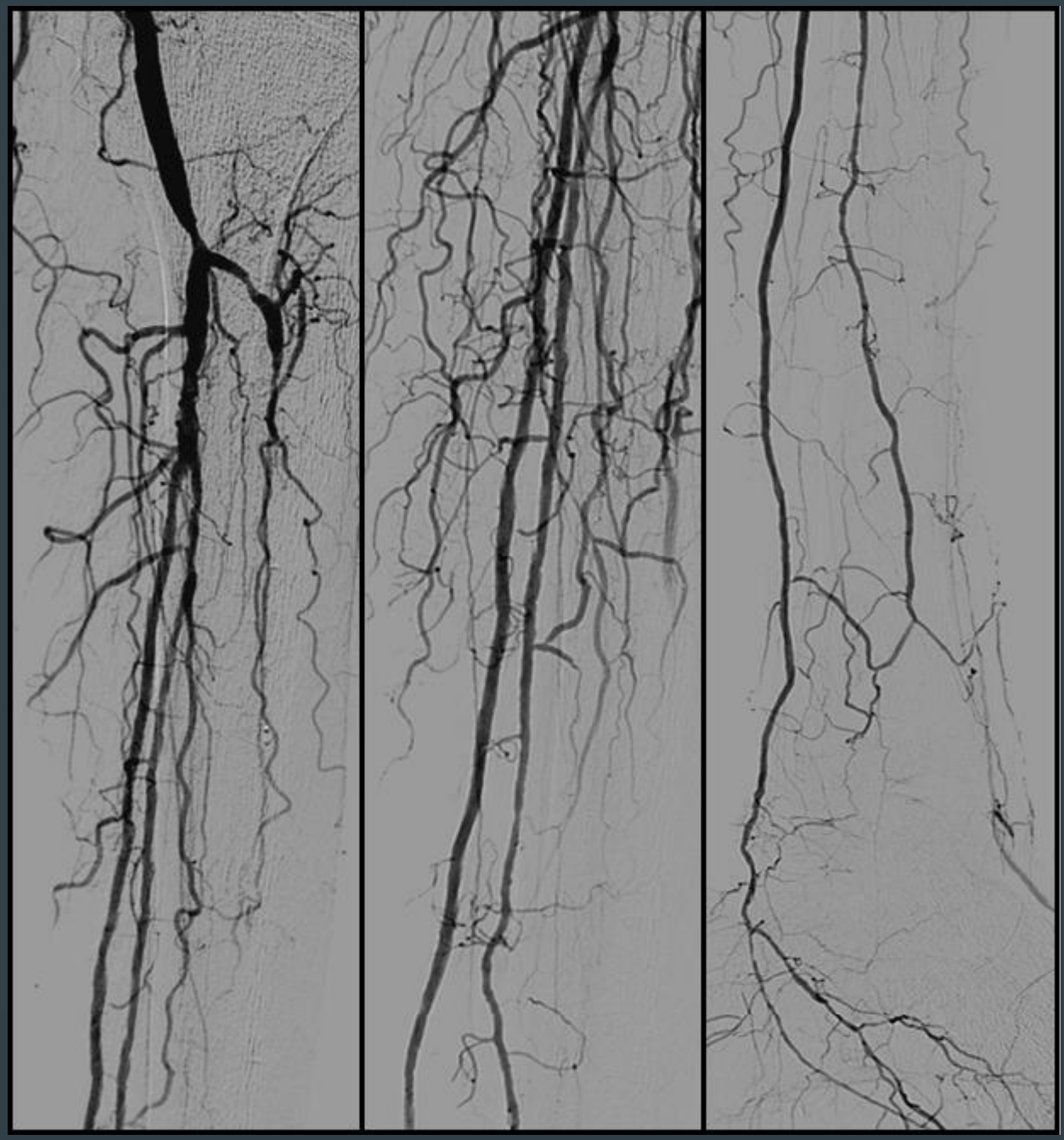
„Results of infrapopliteal angioplasty are better for shorter than for longer lesions“

Trans**A**tlantic Inter-**S**ociety **C**onsensus – *J Vasc Surg* **2007**

CLI due to Long BTK Occlusions

GW-technology and balloon-technology improved significantly since TASC II.





Success-Rate of Angioplasty in Case of Infrapopliteal CTOs

	Failure-Rate
Dorros, *Circulation* 2001	**27 %**
Soder, *JVIR* 2000	**39 %**

Techniques for BTK-Recanalization

Retrograde transpedal or transcollateral angioplasty

Revascularization-success > 95 %

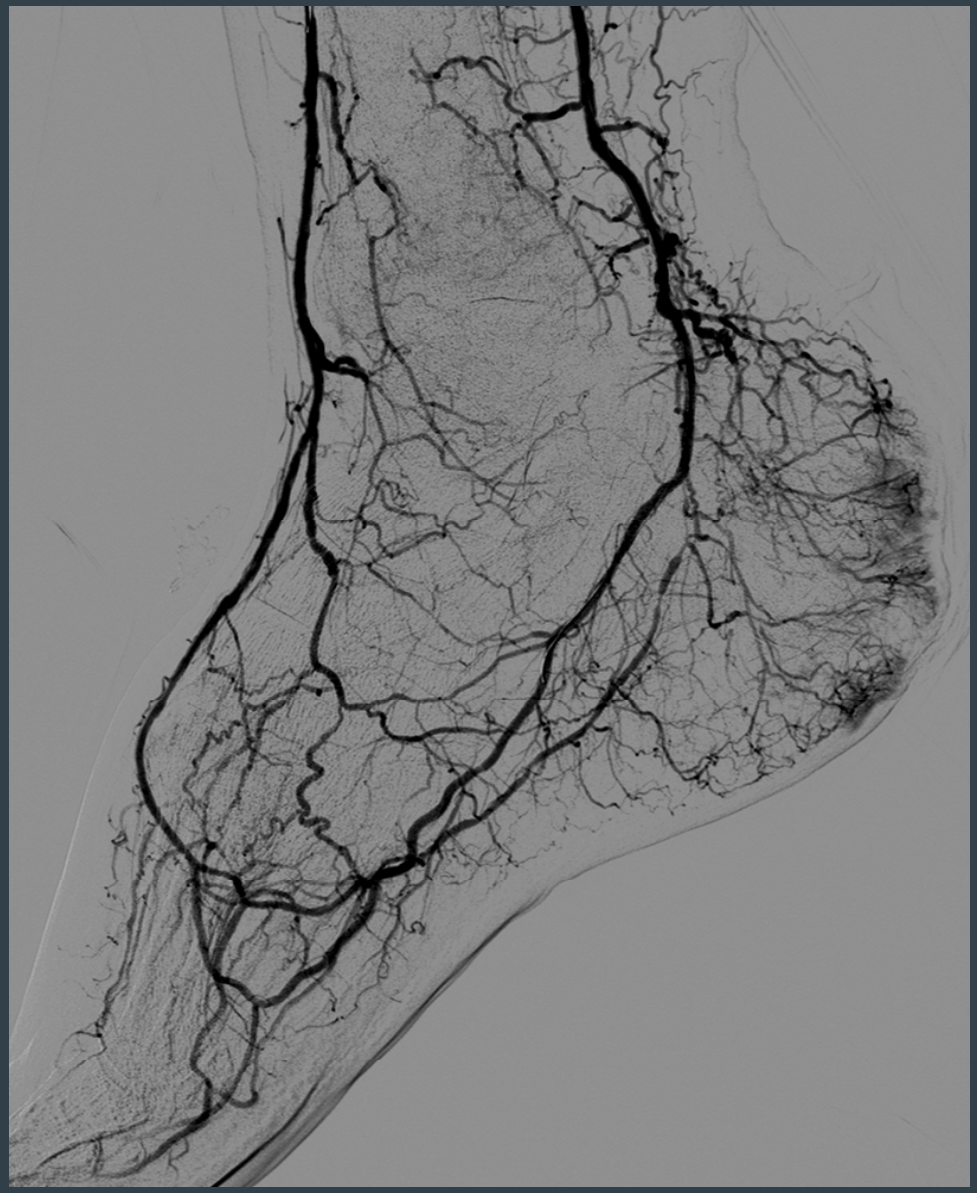
Montero-Baker, Schmidt, et al. *JEVT* 2008;15:594-904

Antegrade passage failed

Retrograde distal Angioplasty

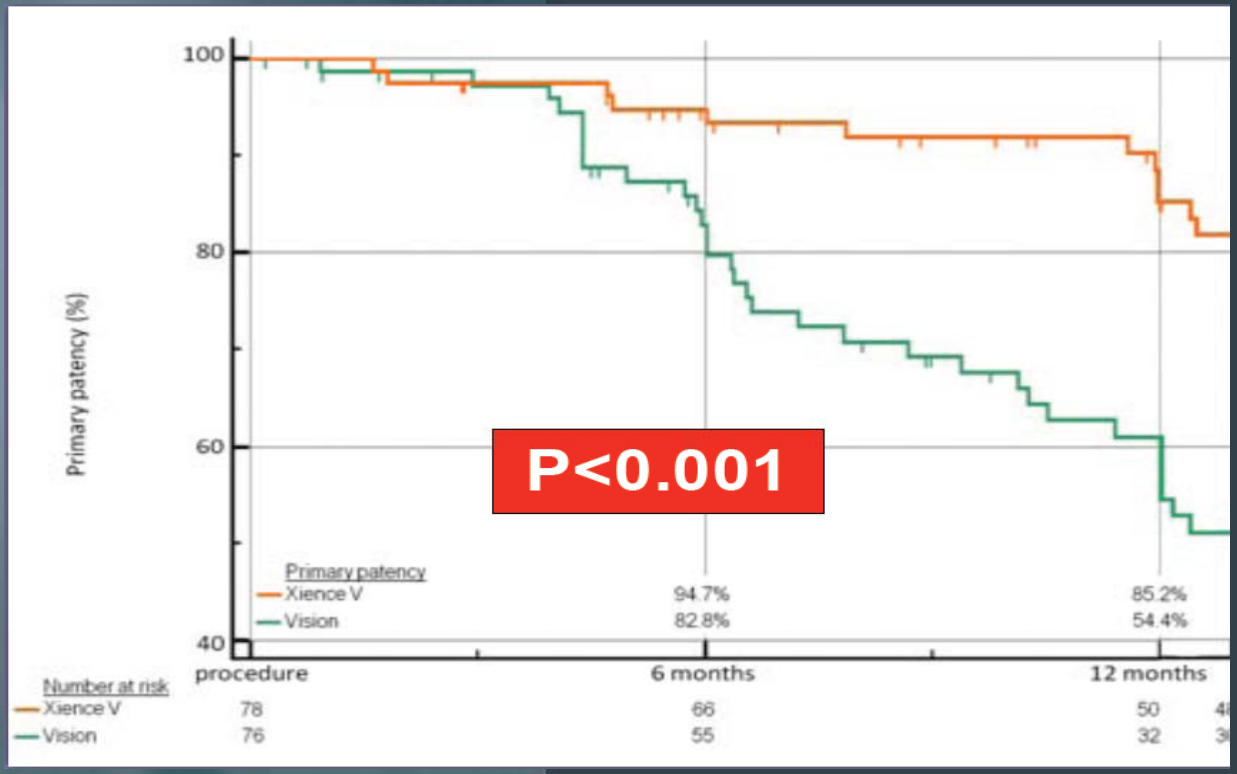
Angioplasty of Plantar Arteries

Angioplasty of Plantar Arteries



RCTs DES vs. BMS BTK

Primary patency (angiographical at 12 months)



85.2% for DES (Xience V)

54.3% for BMS (Multilink Vision)

Bosiers et al. JVS 2011

Similar results for
- ACHILLES (DES vs. Balloon) and
- YUKON (DES vs. BMS).

DESs are an effective treatment-option for short BTK-lesions.

Drug-Eluting Balloons for Treatment of Long Infrapopliteal Lesions

	POB BTK	DEB BTK
Lesion-length	183 mm	173 mm
Restenosis >50 % @ 3 Mo	69 %	27 %
	61% restenosis reduction	
TLR-rate at 12-15 mo	50 %	17 %
	65% TLR-rate reduction	

A. Schmidt et al., *Catheter Cardiovasc Intervent* 2010

Schmidt et al. *JACC* 2011

IN.PACT™ in BTK / CLI / Diabetics

- Preliminary results from a single center RCT of
- IN.PACT Amphirion™ vs PTA BTK in CLI diabetic patients
- Significant reduction in angiographic restenosis rate at **12 mo**

RCT DEB vs. PTA	In.Pact	PTA	p
# Patients	**48**	**44**	
Lesion length (mm)	**121**	**116**	**0.07**
12m RR (Angio)	**27%**	**66%**	**0.0004**
12m re-occlusion	**16%**	**53%**	**0.0006**

F.Liistro, TCT 2011

Conclusion for Infrapopliteal Lesions

Different to the TASC-II recommendations,

infrapopliteal angioplasty can be
first choice therapy for all kind of
BTK-lesions.